



Medical applications of Ionizing Radiation Regulation and control challenges

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Broad range of medical applications:

- **PRACTICE SETTING**
 - *Public hospitals or private clinics*
 - *Large center or proximity health center*
 - *Radiology, interventional cardiology or neurosurgical departments and increasingly operating theaters*
- **APPLICATIONS AND SPECIALISTS**
 - *Diagnosis, guidance or treatments*
 - *Radiologists, interventional radiologists, cardiologists, or surgeons, dentists...*
- **TWO TYPES OF CONTROL**
 - *Prior authorizations per type of application and medical device*
 - *On site inspections to check that regulations are correctly applied*

In 2019, ASN continues to deploy tools for a graded approach to radiation protection oversight.

Implementation of 3 administrative regimes in France



- **NOTIFICATION (*DECLARATION*) SYSTEM**

- Very low hazard activities (conventional radiology, mammography, dental radiology)
- Notification of the activity by the applicant on a dedicated website
- No review process and positive answer with no time limit
- Few or no inspections planned by ASN

- **AUTHORIZATION SYSTEM**

- High hazard activities: patient, professional, public or environment
- Mandatory in France (Public Health Code) for specific medical activities (radiotherapy, brachytherapy, nuclear medicine)
- In depth review and time limited authorizations
- Specific procedure to be followed defined according to field and the applicant status.
- Regular inspections performed by ASN



Implementation of 3 administrative regimes (cont)

Introduction of a new regime

- **THE NEW REGISTRATION SYSTEM (SIMPLIFIED LICENSING)**

- Medium hazard activities: eg CT scan and fluoroscopy-guided interventional practices in operating room (excluding neuroradiology and interventional cardiology)
- Review process of selected topics
- Generic procedures to be followed or no procedure
- Time limited authorizations
- A lower frequency of inspections by ASN

Reinforce the graded approach according to the potential issues involved.

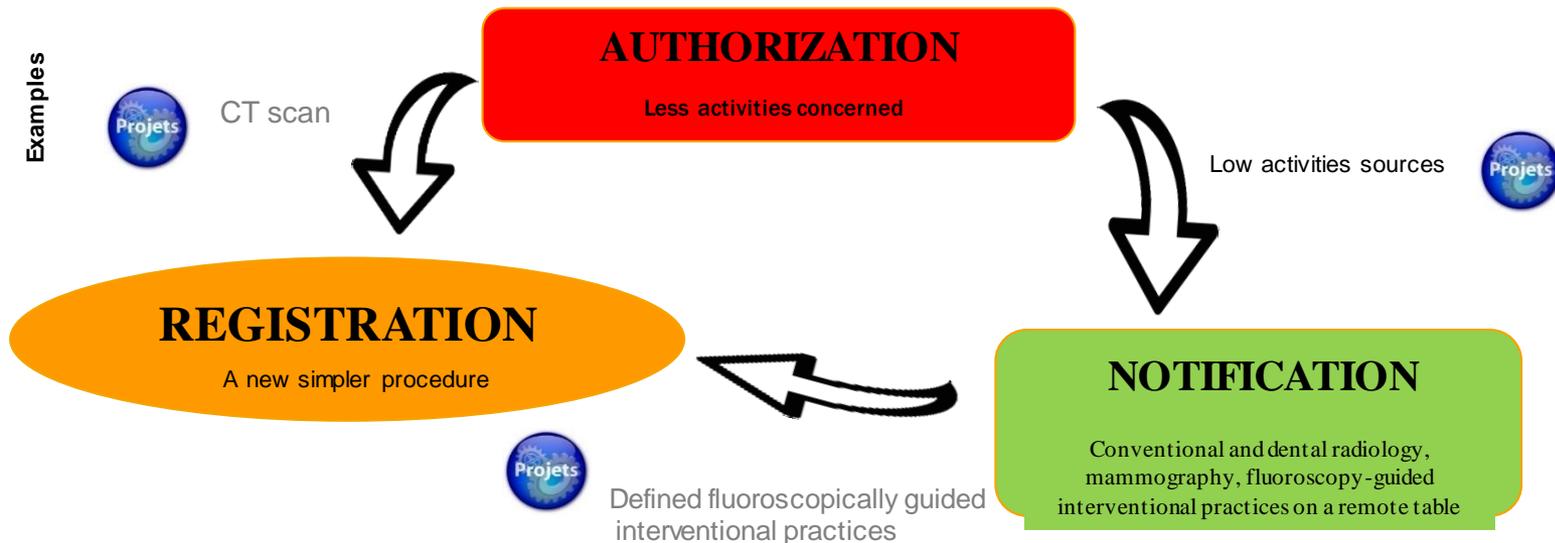


Stake rating for medical activities using ionizing radiations

ACTIVITÉS	PATIENTS	PROFESSIONALS	POPULATION ET ENVIRONMENT
Radiotherapy	3	1	1
Brachytherapy	2	2	2
Vectored internal radiotherapy	3	2	3
Fluoroscopy-guided interventional practices	2 à 3 according to medical act	2 à 3 according to medical act	1
Diagnostic exams in Nuclear Medicine	1 à 2 according to medical act	2 à 3 according to medical act	2
CT scan	2	1	1
Fluoroscopically-guided interventional practices on a remote table	1	1	1
Conventional radiology	1	1	1
Dental radiology	1	1	1

1 : no or very low hazard
2 : medium hazard
3 : high hazard

Our current vision in France



R. 1333-104 à 145



By default if an activity is not listed with **notification** or **registration**



→ **authorization system**

(important pending the publication of notification and registration decisions)



Notification or **registration** or **authorization** : Prerequisite to the exercise of the nuclear activity (before first commissioning),

Rationale of the new CT scan system

- **FROM AUTHORIZATION TO REGISTRATION SYSTEM:**



- The rules of layout of premises hosting CT scan devices provide effective protection of staff, general population and environment.
- In depth review of the application is not required
- On site inspections required to ensure patient protection of patient, e.g. check dose justification and dose optimization
- Patient protection depends mainly on the compliance with good medical practices as regards justification and optimization of examinations.
- These last two points are difficult to assess by studying an application file, and e.g. on-site inspections recommended

Fluoroscopically-guided interventional practices

- **FROM NOTIFICATION TO REGISTRATION REGIME:**
 - Higher risks for patients in given practices, e.g. interventional surgery in the operating theater.
 - Higher risks for professionals, e.g. repeated and lengthier activities in the operating theater.
 - Multiple priorities to manage in an operating room
 - Extensive work to raise professionals' awareness in order to comply with radiation protection rules.
 - Choice of a registration system (simplified licensing)

Thus in the medical field, the inspections of fluoroscopy-guided interventional practices were most numerous, while the number of CT inspections fell significantly.

Implementation of a new inspection strategy

➤ **INITIATED IN 2018, A STRATEGY BASED ON 2 PRINCIPLES:**

- **Systematic checks**
 - Focus: compliance with regulations relating to workers, patients and general public protection.
 - Scope: predefined and limited number of essential check-points, associated to pre-defined indicators for facilitating cross-evaluations at regional and national level.
 - Eighteen (18) essential check-points chosen for fluoroscopic-guided interventional procedures. For each point, expectations, documents to be consulted, interviews and direct observations in the field were defined.
- **In-depth investigations**
 - Priorities for in-depth investigations during inspections are defined according to the specific features of the facility, the on-site observations, the findings from previous inspections, etc.
 - ASN sets the frequency of inspections in each facility according to the type of medical applications.

A new ASN resolution for medical imaging QA

➤ APPLIED SINCE JULY 1ST 2019, AND SETTING THE QUALITY MANAGEMENT OBLIGATIONS:

- It defines the QA obligations and mainly focusses on:
 - continuing education;
 - work station habilitation
 - reporting of adverse events.
- Its application will be checked:
 - through inspections for main activities with the most significant potential consequences (high or medium hazard)
 - through enquiries sent to the professionals; they have to describe the implementation of the regulation. Further inspections may subsequently be planned according to the answers.

A pragmatic and systematic approach taking into account:

- the risk level for a given medical activity
- the number of acts performed in each medical category
- Applicant's equipment and human resources
- ASN workforce
- administrative choices for licensing regimes adjusted to stake rating

Cumulative experience review required to evaluate the relevance of our strategy.



Anticipating technological changes:

- A committee to analyze new medical practices or technologies using ionizing radiation set up in 2019 in order to ensure that they are deployed under the best radiation protection conditions for patients, personnel and the environment.
- This committee could notably recommend prospective data collection and support measures for professionals.





Thank you for your attention